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09/922,013	08/03/2001	Mark Rutenberg	1373.016	1064

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 07/30/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-7

Office Action Summary

Application No.

09/922,013

Applicant(s)

RUTENBERG ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21, 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Election/Restrictions

1. Claims 1-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 3.

2. This application contains claims 1-15 drawn to an invention nonelected with traverse in Paper No. 3. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

3. The drawings are objected to because the instant disclosure includes both "Diagrams" and "Figures". As indicated in 37 CFR 1.84 all of the drawings should be identified as "Fig.". Also the "Brief Description of the Drawings" should also be updated so as to reflect six drawings rather than three and reference all of the drawings as "Fig.". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

In response to Applicants' comments concerning the drawings, Applicants comments are specific to Figures 1-3 which appear to be cell images and not block diagrams. The block diagrams appear to be referenced in the instant disclosure as "Diagrams". As mentioned above, clarification would be facilitated by referring to all of the drawings a "Fig.". Correction and/or clarification is requested.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 16-21 and 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-21 and 23-27 are drawn to “a system to detect cancerous and precancerous cells”. The bodies of the claims merely recite a computer. In the absence of further positively recited structural elements, it is not clear how the computer is capable of detecting cells as intended by the preamble of the claim. How is the cell sample interfaced with the computer?

In claims 17, 23, 25 and 27, it is not clear how the language of these claims further limits the structure of the device recited in claim 16. While the claim language may be more specific it is not clear how this claim language further limits the structure of the system which is encompassed by a computer which already is capable of morphological and cytometrical analysis of a cell sample. Note claims 23 and 27 appear to be a method step and not a clearly defined structural limitation.

In new claims 24-27, it is not clear how the recited brush structurally cooperates with the claimed computer so as to provide the intended function of the claimed system.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutenberg et al.(US 5,740,270).

The reference of Rutenberg et al. discloses a system which is capable of detecting cancerous and precancerous cells in a cell population which includes a computer (20) which includes a primary classifier and secondary classifier which identify individual cells for atypicality in terms of cell morphology and cytometry. After the cells are identified and

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locations stored in the computer, the system is able to select suspect cells for further analysis, tertiary classification, including manual classification (See column 4, lines 39-55; column 5, lines 5-7; and column 8, lines 35-60). The system of Rutenberg et al. is capable of identifying the suspect cells as is required of the instant claims.

While the reference of Rutenberg et al. discusses the use of DNA ploidy analysis the disclosed embodiment does not include this limitation as recited in the instant claims which recite "means to conduct DNA ploidy quantization of said atypical cells".

The reference of Rutenberg et al. discloses that the disclosed system is capable of DNA ploidy analysis and molecular detection methods. The reference discloses that DNA ploidy analysis and/or molecular detection methods may be used as an additional means to classify the atypical cells (See column 14, lines 15-40).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ DNA ploidy analysis and/or molecular detection methods in addition to the primary and secondary classification disclosed by the reference of Rutenberg et al. for the known and expected result of providing additional means recognized in the art to further classify and/or detect atypical cell samples among a plurality of cells on a sample field.

10. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutenberg et al.(US 5,740,270) in view of Bacus (US 5,526,258).

The reference of Rutenberg et al. has been discussed above.

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The above claims differ by reciting that the computer plots a histogram and employs a light indicator to show DNA ploidy.

The reference of Bacus discloses that when using a computer to perform DNA ploidy it is conventional in the art to employ histograms and light indicators to show DNA ploidy of selected cells (See Figures 3-6 and 12).

In view of this teaching, when performing DNA ploidy as suggested by the reference of Rutenberg et al., it would have been obvious to one of ordinary skill in the art to program the computer so as to display the results in the form of histograms and light indicators for the known and expected result of providing a conventional means in the art to display DNA ploidy information which has been determined by a computer.

11. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutenberg et al. (US 5,740,270) in view of Hicken (US 5,184,626).

The reference of Rutenberg et al. has been discussed above.

The claims differ by requiring the presence of a brush for sampling cells.

The reference of Hicken discloses a sampling device (abrasion or brush sampling devices) which are known in the art for obtaining a cytological tissue sample which is used to detect abnormal cells. These brush devices are structurally capable of providing the level of sampling required of the claims.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the sampling means of the secondary references for obtaining the sample required for the device of the primary reference for the known and expected result of providing a structure

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known in the art for obtaining a cytological sample as is required of the system of the reference of Rutenberg et al.

Response to Arguments

12. Applicant's arguments filed 07 June 2002 have been fully considered but they are not persuasive.

Applicants argue that the reference of Rutenberg et al. merely generally discloses that other morphological algorithms may be alternatively or additionally used to classify and also argues that the reference does not show, suggest or disclose conducting DNA ploidy quantization on selected atypical cells.

Applicants' comments are not persuasive because the reference of Rutenberg et al. clearly suggests that additional morphological algorithms may be used which include DNA ploidy analysis, immunohistochemistry and DNA hybridization (See column 14, lines 26-40). One of ordinary skill in the art would recognize that the use of further known classification techniques would provide enhanced accuracy in selecting atypical cells.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**


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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB
July 29, 2002